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Paul E. Rauch, Ph.D.
BRINKS HOFFER GILSON & LION
P.O. Box 10395
Chicago, IL 60610

EXAMINER

NICKOLLA, CLAYTON

ART UNIT

PAPER NUMBER

1042

DATE MAILED: 03/26/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/684,458

Applicant(s)

GERRITSEN ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-65 and 67-112 is/are pending in the application.
- 4a) Of the above claim(s) 1-23, 36-59, 64, 65 and 68-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 24-35, 60-63 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1 ☐ Certified copies of the priority documents have been received.
- 2 ☐ Certified copies of the priority documents have been received in Application No. _____.
- 3 ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

The Amendment filed November 18, 2002 (Paper No. 16) in response to the Office Action of June 18, 2002 is acknowledged and has been entered.

Claim 66 was cancelled.

Claims 1-65, 67-112 are pending in the application.

Claims 1-23, 36-59, 64-65, and 68-112 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 24-35, 60-63, and 67 are currently under prosecution

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Oath/Declaration

The oath or declaration remains defective for the reasons of record in Paper No. 14, page 3. Applicants acknowledge the errors, but have opted not to correct the deficiencies at this time.

Specification

For the record, Applicant's substitute specification has been entered into the record; however, the disclosure remains objected to for the reasons of record because it contains an embedded hyperlink and/or other form of browser-executable code (i.e. see page 37, line 8; page 39, line 25). Applicant is required to delete all embedded hyperlinks and/or other form of

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browser-executable codes. See MPEP § 608.01. Applicants did not address this issue in their response in Paper No. 16.

Rejections Withdrawn:

The rejection of Claims 24-35, 60-63, 67 under 35 U.S.C. 101 is withdrawn in view of applicant's arguments there to.

Objections Maintained:

Claim 63 remains objected for the reasons of record in Paper No. 14, page 4 with regards to recitation of "or antibody".

Rejections Maintained:

Claims 24-35, 60-63, 67 remain rejected under 35 U.S.C. 112, first paragraph because one skilled in the art would not know how to use the claimed invention.

Applicants argue (Paper No. 16, page 4) that the utility of the PRO-C-MG.2 polypeptide (SEQ ID NO:2) is credible because PRO-C-MG.2 is up-regulated during angiogenesis. This argument has been found persuasive with regards to the issues of utility. However, the claims are drawn to isolated polypeptides, not the genes encoding them, and applicants have not shown sufficient guidance and or objective evidence of the polypeptide's isolation and or a credible use for the polypeptide for the reasons of record. As recited in the previous action, those of skill in

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the art recognize that expression of mRNA, specific for a tissue type, does not necessarily correlate nor predict similar levels of translation of such mRNA into a polypeptide nor predict that such a polypeptide will actually be produced. Thus, the predictability of protein translation is not necessarily contingent on mRNA expression due to the multitude of homeostatic factors affecting transcription and translation. Applicant's have argued (Paper No. 16, page 5) that the above is merely an exception and that there is no evidence that PRO-C-MG.2 is an exception to the rule that genes are regulated transcriptionally. This argument has been considered but is not found persuasive. Assuming arguendo, that applicants did reveal translation of the polypeptide, such as through Western blot data, there remains to be seen any evidence that the polypeptide would be used by one skilled in the art in any predictable manner, such as to affect angiogenesis and or tumor neovascularization. Any increase in expression of PRO-C-MG.2 says nothing about the purported biological properties of the PRO-C-MG.2 *polypeptide*. For example, these results do not say whether or not the PRO-C-MG.2 promotes angiogenesis or prevents angiogenesis. Many genes are overexpressed in many different tissues types, and it remains to be determined whether such overexpression translates into a polypeptide or whether such a polypeptide would be useful to one of ordinary skill in the art. Applicants' have pointed to the specification on pages 28 and 29 to support the conclusion that the PRO-C-MG.2 polypeptide is involved in the neovascularization of tumors. This argument has been considered but is not found persuasive because no such support could be found on pages 28 and 29 of applicant's disclosure. Further, as pointed out in the previous Action, the examples in the specification are prophetic and would require further experimentation. For example, the specification teaches (page 144, lines 8+) the in vivo anti-angiogenic effects of a PRO-C-MG.2 polypeptide

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antagonist are "shown" using Hydron pellets, and that these in vivo data (line 15) are consistent with the in vitro results. However, no such data has been presented to verify such activity. Thus, for the reasons of record and for the reasons set forth above, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 24, 26, and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record in Paper No. 14, pages 9-10.

Applicants argue (Paper No. 16, page 6) that a written description of an invention involving a chemical genus requires a precise definition, such as by structure or formula of the claimed subject matter sufficient to distinguish it from other materials. Applicants add that since one skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass, such a formula is normally an adequate description of the claimed invention. This argument has been considered but is not found persuasive for the reasons of record. The written description in this case only sets forth SEQ ID NO:2 and therefore the written description is not commensurate in scope with the claims drawn to polypeptides with "80% sequence identity" or those "scoring at least 80% positives", or "fragments sufficient to provide a binding site" or polypeptides produced by hybridizing test DNA molecules under stringent conditions and culturing a host cell comprising the test DNA molecule under conditions

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suitable for the expression of the polypeptide; all of which read on naturally occurring variants of SEQ ID NO. 2. As set forth in the prior Action, with the exception of SEQ ID NO:2, the skilled artisan cannot envision the detailed structure of the encompassed polypeptide fragments and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Further, the presentation of SEQ ID NO:2 is not an adequate representation of a genus because the disclosure fails to describe the common attributes or characteristics that identify other members of the genus. Because the genus is highly variant, the claiming of nonspecific amino acid sequences (fragments, portions, etc.) is insufficient to describe the genus and full-length genes. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe a genus. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

New Objections:

Claim 26 is objected to for reciting "about" as it renders the claim grammatically unclear.

All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to. No claim is allowed.

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Conclusion

Applicant's amendment necessitated the new ground(s) of objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Gary B. Nickol Ph.D.

Examiner

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GBN

March 20, 2003

